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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,686	10/26/2000	Keith D. Allen	3866-4	4566

7590 02/22/2002

NIXON & VANDERHYE P.C.
8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/22/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/696,686	ALLEN, KEITH D.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-47, 53-56, drawn to cells comprising a disruption in a target DNA sequence encoding a TRP, a non-human vertebrate comprising a disruption in a gene encoding TRP, a method of identifying agents capable of affecting a phenotype of a knockout mouse, classified in class 800, subclass 3, 8, 9, 11, 13, 18, 21, 22, 25, class 435, subclass 455, 463, 320.1, 325, class 424, subclass 9.2, for example.

II. Claim 48, drawn to an undisclosed agent, unclassifiable.

III. Claims 49-52, drawn to a method of determining whether expansion of the trinucleotide repeat in a gene encoding a TRP produces a phenotypic change, classified in class 435, subclass 4.

IV. Claim 57, drawn to a method of identifying agents capable of affecting a phenotype of a knockout cell line, classified in class 435, subclass 4, for example.

V. Claims 58-60, drawn to cell lines comprising a nucleic acid sequence encoding a TRP operably linked to a promoter functional in the cell line, classified in class 435, subclass 325, 320.1, for example.

VI. Claims 61-63, drawn to the TRP protein, classified in class 530, subclass 350+, for example.

VII. Claims 64-65 drawn to a nucleic acid sequence encoding the murine TRP or human TRP, classified in class 536, subclass 23.5, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and any of Inventions II, VI are distinct products, which are distinct in chemical structure and function. The cells, non-human vertebrate and

method of identifying agents of Invention I are not required for the undisclosed agent of Invention II, and the TRP protein of Invention VI, and vice versa.

Inventions I and either of Inventions III or IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Invention I can be used to produce protein *in vitro*, and the transgenic non-human vertebrate can be used as models for disease.

Invention I and either of Inventions V or VII are distinct. The transgenic non-human vertebrate Invention I can be used as a model for disease. The cell line of Invention VI can be used to produce protein *in vitro*. The nucleic acid of Invention VII can be used as a detection probe.

Invention II and any of Inventions III-VII are mutually exclusive and independent. The undisclosed agent of Invention II is not required for the implementation of the method of determining whether expansion of the trinucleotide repeat in a gene encoding a TRP produces a phenotypic change of Invention III, the method of identifying agents capable of affecting a phenotype of a knockout cell line of Invention IV, the cell lines comprising a nucleic acid sequence encoding a TRP operably linked to a promoter functional in the cell line of Invention

V, the TRP protein of Invention VI, and the nucleic acid sequence encoding the murine TRP or human TRP of Invention VII, and vice versa.

Invention III and any of Inventions IV-VII are mutually exclusive and independent. The method of determining whether expansion of the trinucleotide repeat in a gene encoding a TRP produces a phenotypic change of Invention III is not required for the implementation of the method of identifying agents capable of affecting a phenotype of a knockout cell line of Invention IV, the cell lines comprising a nucleic acid sequence encoding a TRP operably linked to a promoter functional in the cell line of Invention V, the TRP protein of Invention VI, and the nucleic acid sequence encoding the murine TRP or human TRP of Invention VII, and vice versa. Note further that each of the methods of Inventions III and IV requires a materially different and separate protocol.

Invention IV and any of Inventions V-VII are mutually exclusive and independent. The method of identifying agents capable of affecting a phenotype of a knockout cell line of Invention IV is not required for the implementation of the cell lines comprising a nucleic acid sequence encoding a TRP operably linked to a promoter functional in the cell line of Invention V, the TRP protein of Invention VI, and the nucleic acid sequence encoding the murine TRP or human TRP of Invention VII, and vice versa.

Invention V and either of Inventions VI or VII are distinct products, as each is distinct in chemical structure and function, as well as therapeutic function. Each

of the Inventions can be used in materially different methods. The cell lines of Invention V can be used in *in vitro* binding assays, the TRP protein of Invention VI can be used for antigen presenting cell priming, and the polynucleotides of Invention VII can be used as detection probes.

Inventions VI and VII are distinct products, as each is distinct in chemical structure and function, as well as therapeutic function. Each of the Inventions can be used in materially different methods. The TRP protein of Invention VI can be used for antigen presenting cell priming, and the polynucleotides of Invention VII can be used as detection probes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800 1630

TNT
Thaian N. Ton
Patent Examiner
Group 1632